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Guidance for the Reregistration of Wood Preservative Pesticide Products Containing Chromated and Non-Chromated Arsenicals as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF WOOD PRESERVATIVE
PESTICIDE PRODUCTS
CONTAINING
CHROMATED AND NON-CHROMATED ARSENICALS
AS THE ACTIVE INGREDIENT

CASE NUMBER 0647

[CAS (DOCKET) NUMBER OF INGREDIENT OR PRINCIPAL INGREDIENT]

September 10, 1986

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield Virginia 22161 approximately 90 days after issuance and are available from the Registration Division Product Manager prior to that time.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of chemicals

This registration standard covers the active ingredients, containing arsenic and chromium in products intended for use as wood preservatives. The six arsenic compounds used in the formulation of wood preservatives are arsenic pentoxide, arsenic trioxide, arsenic acid, ammonium arsenate, sodium arsenate, and sodium pyroarsenate. All but two of these compounds, arsenic trioxide and ammonium arsenate, are complexed with chromium when formulated into end-use wood preservative products. The four chromium compounds used in the formulation of wood preservatives are chromic acid, sodium chromate, sodium dichromate, and potassium dichromate.

For both arsenic and chromium, multiple valences exist. The majority of arsenic is present in the pentavalent state (arsenate, +5), although some trivalent (arsenite, +3) arsenic has been found. Chromium is usually present in the hexavalent state (chromate, +6), but is also found in the trivalent state (chromite, +3).

The general formulations of the products covered by this standard can be described as [X]CrAs or [X]As. [X] is usually an ionic form of copper, pentachlorophenate, 2,4-dinitrophenol, or ammonia. Varying formulations exist within each group. The major use group is copper chromated arsenates. There are three basic formulas within this group. The original formulation is now referred to as CCA-type A (chromium/arsenic ratio of 2.73), the use of which is limited today. Updated versions, CCA-B and CCA-C (chromium/arsenic ratios of .54 and .96 respectively), are now available and were designed to be even more tightly retained by the wood that is treated, than the original formulation.

Arsenic and chromium are commodity chemicals with many non-pesticidal uses, and the active ingredients incorporated into the formulated products are not always registered as manufacturing use products.

CHROMIUM USED IN WOOD PRESERVATIVE FORMULATIONS

Compound	Empirical Formula	Molecular Weight[a]	CAS Registry Number	Shaughnessy Number
Chromic acid	CrO_3[b]	100.01	07738-94-5	021101
Sodium chromate	Na_2CrO_4[c]	161.97	07775-11-3	068303
Sodium dichromate	$Na_2Cr_2O_7$[d]	261.96	10588-01-9	068304
Potassium dichromate	$K_2Cr_2O_7$	294.21	07778-50-9	068302

[a] Values are for the anhydrous form.
[b] Actually, the true chromic acid (H_2CrO_4) exists in solution.
[c] Most likely would exist as the decahydrate ($Na_2CrO_4.10H_2O$) in solution.
[d] Would probably exist as the dihydrate ($Na_2CrO_4.2H_2O$) in solution.

ARSENICALS USED IN WOOD PRESERVATIVE FORMULATIONS

Compound	Empirical Formula	Molecular Weight	CAS Registry Number	Shaughnessy Number
Arsenic acid	H_3AsO_4	141.94	7778-39-4	006801
Arsenic pentoxide	As_2O_5	229.84	1303-28-2	006802
Arsenic trioxide	As_2O_3	197.8	1327-53-3	007001
Ammonium arsenate	$(NH_4)_2HAsO_4$	175.92	53404-17-4	013601
Sodium arsenate	$Na_3AsO_4.12H_2O$	423.9	10048-95-0	013505
Sodium pyroarsenate	$Na_4As_2O_7$	353.8	13464-12-1	013401

B. Use Profile

Type of Pesticide: Wood Preservative
Pests Controlled: Fungi, Insects, Bacteria, and Marine Borers
Registered Uses: Wood Preservative/Commercial Application
Methods of Application: Pressure Treatment and Brush on Application (Cut Wood Ends/Construction Sites Only)

Formulation Types Registered:

Registered Technicals: 90%, 94%, 95.5%, 99% Arsenic trioxide

98% Ammonium arsenate

98.88% Sodium arsenate

End Use:
- Soluble Concentrate/Liquid (SC/L) 3%-75%
- Soluble Concentrate/Solid (SC/S) 4.8%-23.9%
- Granular (G) 1.5%
- Impregnated Materials (IM) .46%
- Liquid-Ready-To-Use (L/RTU) 1.5%-21.2%
- Wettable Powder (WP) 20%

Physical Characteristics: The Agency is requiring information on the source and description of arsenic, chromium, and other active ingredients in the formulated end-use products to determine the characteristics of each product.

C. Regulatory History

The Environmental Protection Agency issued a Notice of Rebuttable Presumption Against Registration (hereafter referred to as Special Review) for the wood preservative uses of the inorganic arsenicals on October 18, 1978 (43 FR 48267). That notice was based on a determination that the use of the inorganic arsenical pesticide products met or exceeded the risk criteria for oncogenicity, mutagenicity, and teratogenicity under 40 CFR 162.11, now found at 40 CFR 154.7.

In January 1981, the Agency issued a preliminary regulatory determination (46 FR 13020) which proposed changes to the terms and conditions of registration for inorganic arsenicals intended for use as wood preservatives. That proposal was based on a detailed assessment of the risks and benefits of continued registration (PD 2/3); the Agency concluded that the benefits of use were high and that measures short of cancellation could be implemented to reduce the risks to an acceptable level. The final determination was published in the FEDERAL REGISTER of July 13, 1984 (49 FR 28666). The Agency received hearing requests from registrants contesting the requirements of the July 13, 1984 final determination. After considering certain alternative mechanisms suggested by registrants for accomplishing the goals set out in the July 13 determination, the Agency published in the FEDERAL REGISTER of January 10, 1986 (51 FR 1334) an amended notice. The changes made to the requirements of the original notice were minor in scope.

While the Special Review only addressed the inorganic arsenic component of arsenical wood preservative products, this standard addresses chromium in addition to inorganic arsenic because chromium is often complexed with arsenic in formulated wood preservative products.

Both arsenic and chromium have been extensively reviewed by EPA's Office of Health and Environmental Assessment (OHEA), Office of Research and Development. The following final reports prepared by OHEA are the main source documents for the science assessment contained in this document:

> Health Assessment Document for Inorganic Arsenic. Final Report. EPA-600/8-83-021F. Office of Health and Environmental Assessment, U.S.E.P.A., Washington, D.C. March 1984.

> Health Assessment Document for Chromium. Final Report. EPA-600/8-83-014F. Office of Health and Environmental Assessment, U.S.E.P.A., Washington, D.C. August 1984.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has conducted a thorough review of the scientific data base for the inorganic salts of chromium and arsenic. The results of this review are summarized below and discussed in greater detail in Section III.B. of this document and in the support documents mentioned above.

1. Inorganic arsenic and hexavalent chromium compounds are classified as Group A carcinogens (evidence of human carcinogenicity). There is currently sufficient evidence from epidemiologic studies to support an association between exposure to both chemicals and cancer. No further oncogenicity studies will be required.

a. Inorganic arsenic compounds are both lung and skin carcinogens in humans.

(1). Studies among smelter workers and among workers engaged in the production and use of arsenical pesticides have demonstrated excess mortality due to lung cancer.

(2). A study of a non-occupational population within Taiwan exposed to high concentrations of arsenic in well water has demonstrated excess occurrences of skin cancer. The Agency is currently reevaluating the risk model for oral and dermal exposure to inorganic arsenicals.

b. Hexavalent chromium is a lung carcinogen in humans. Exposed workers in chromate refining plants showed significantly increased levels of respiratory carcinomas.

2. Both arsenic and chromium have demonstrated the potential to cause teratogenic/fetotoxic effects.

a. Studies in which arsenate and chromium compounds were administered intravenously or intraperitoneally to hamsters, rats, and mice, demonstrated gross malformations (terata) and fetotoxic effects; however, the routes of exposure were not appropriate for human risk assessment.

b. Oral studies for arsenic in mice are deficient because they either failed to produce gross malformations in offspring or have produced only a slightly increased incidence of gross malformations and only at dosage levels that have also caused significant maternal mortality. Therefore, no-observable-effect-levels (NOELs) for maternal toxicity and teratogenic/fetotoxic effects could not be determined from these studies.

c. Oral studies for chromium are not available.

In order to better define teratogenic or fetotoxic effects for arsenic which may occur below maternally toxic levels, the Agency has required two oral teratology studies; one with rabbits, the other with hamsters or mice, using sodium arsenate or arsenic pentoxide (See Special Data Call-In Notice on Wood Preservatives Containing Inorganic Arsenicals, April 7, 1986). Further, the Agency is requiring oral studies to determine teratogenic and fetotoxic potential of chromium using a formulated chromated arsenical product. (See Data Appendix for due dates of these studies).

3. Due to the Agencys concern about teratogenic/fetotoxic effects of both chromium and arsenic, the Agency is requiring a reproduction study using a formulated chromated arsenical product unless a metabolism study demonstrates that blood levels of chromium and arsenic are not increased above background levels.

4. The Agency does not have adequate data to determine the bioavailability of chromium and arsenic after exposure to a formulated product. Metabolism data are required to assess the bioavailability of these chemicals.

5. Short term assays indicate that hexavalent chromium and trivalent and pentavalent arsenic are mutagenic. No mutagenicity data are being required.

In addition to the studies noted above, the Agency has identified ecological effects and environmental fate data which are needed to evaluate the environmental and human risks associated with the use of chromated and non-chromated arsenicals. These data must be developed in order to maintain registrations of products or register new products containing chromated and non-chromated arsenicals. The table in this section summarizes all the data gaps, in addition to product chemistry information. Please note that this is only a summary and more details can be obtained by referring to Tables A, B, and C, Section D of Part II.

Further, the Agency has determined that labeling revisions or restrictions in the following areas are necessary:

- classification of all uses as restricted, except for the commercial brush on use.
- protective clothing and equipment requirements.
- prohibitions against eating, drinking, or smoking during application.

- requirements for proper care and disposal of work clothing and equipment
- requirements for proper disposal of pesticide waste.
- requirements for using respirators in arsenic pressure treatment plants when arsenic ambient air levels are unknown or exceed 10ug/m^3 over an 8 hour period (Permissible Exposure Limit Moonitoring Program).
- adherence to industry standards to reduce surface residues of arsenic on treated wood.
- using closed systems for mixing and emptying powdered formulations of inorganic arsenicals.

SUMMARY OF DATA GAPS FOR WOOD PRESERVATIVE PESTICIDE PRODUCTS CONTAINING CHROMATED AND NON-CHROMATED ARSENICALS
([X]CrAs and[X]As)

DATA REQUIREMENT	REMARKS *
ENVIRONMENTAL FATE	
SPECIAL STUDIES - Aqueous, soil and air availability	[Cr] & [As] applied end use products **
Aerobic Soil	[As]
Anaerobic Aquatic	"
Aerobic Aquatic	"
Volatility	[As], [Cr], & [X]
TOXICOLOGY	
Acute Oral	All MPs & EPs
Acute Dermal	" " " "
Acute Inhalation	" " " "
Eye Irritation	" " " "
Dermal Irritation	" " " "
Dermal Sensitization	" " " "
Teratology	Sodium arsenate or arsenic pentoxide and Formulated chromated arsenical
Reproduction	Formulated chromated arsenical
General Metabolism	Formulated chromated arsenical
WILDLIFE AND AQUATIC ORGANISMS ***	
Avian Oral LD_{50}	Formulated chromated arsenical
Avian Dietary LC_{50}	" " "
Freshwater Fish LC_{50}	" " "
Freshwater Aquatic Invertebrate LC_{50}	" " "
Estuarine and Marine Organism LC_{50}	" " "
Fish Early Life-Cycle and Invertebrate Life-Cycle	" " "
PRODUCT CHEMISTRY	
Product Identity and Composition	Technicals, MPs, EPs, &
Analyis and Certification of Product Ingredients	" " "
Physical and Chemical Characteristics	Technicals

---

* Indicates test material

** Tests must determine the availability of Cr & As from treated wood after application of a formulated chromated arsenical product.

*** Additional chronic aquatic testing reserved pending review of required acute, subchronic and availability studies

B. PRELIMINARY RISK ASSESSMENT FOR INORGANIC ARSENIC AND CHROMIUM

1. INORGANIC ARSENIC

a. Risks

There is an extensive body of information available on the salts and oxides of arsenic from literature and other sources. Therefore, although the Agency does not have specific studies on the individual inorganic arsenical wood preservative chemicals, it is not requiring additional data under FIFRA, in many cases. This risk assessment relies primarily on the OHEA document on inorganic arsenic referred to previously. This and other documents mentioned are cited in the Bibliography (Appendix IV).

(1). Metabolism

Arsenic exists primarily in two different valence states, pentavalent (arsenate, +5) and trivalent (arsenite, +3). Of the two, the trivalent state is more acutely toxic. Recent analytical techniques which permit the chemical speciation of arsenic into its various forms have elucidated the metabolism of arsenic in the animal body. Two processes, oxidation-reduction and methylation, have been indicated as the mechanisms involved. These two processes may occur sequentially or methylation may be the sole mechanism. These two processes are summarized below:

(a). An _in-vivo_ oxidation-reduction interconversion of pentavalent and trivalent inorganic arsenic, with the trivalent form predominating.

(b). An _in-vivo_ methylation of inorganic arsenic resulting in the formation of monomethyl and dimethyl organic arsenic compounds which are subsequently excreted.

Administration of either pentavalent or trivalent arsenic to experimental animals or humans results in the formation of methylated inorganic trivalent arsenic. The _in vivo_ methylation process has been observed in every mammalian system studied to date (except in the Marmoset monkey) and is believed to be a detoxification mechanism. In man about 75% of the total excreted arsenic is in the form of dimethyl arsenic.

Retention of arsenic in skin, hair, and nails is regarded as an excretory mechanism into a physiologically inactive compartment. Generally, arsenic does not accumulate in physiologically active compartments of the mammalian body. Rats, however, bind arsenic to erythrocytes which results is delayed distribution to the tissues. The biological half-life of arsenic in rats is up to 90 days as compared to a biological half-life of several days in other mammalian species. For this reason, the rat is not an appropriate test species to determine potential effects of arsenic in other mammalian species, especially humans.

The major excretory route of arsenic in animals and humans is via the urine. Renal clearance is very rapid.

(2). Oncogenicity

The Agency has performed an assessment of the weight-of-evidence for carcinogenicity of inorganic arsenicals. Based on epidemiological studies in humans and on other supportive studies and information, it was concluded there is sufficient evidence that inorganic compounds of arsenic are both lung and skin carcinogens in humans. According to the Agency's draft Guidelines for Carcinogen Risk Assessment (January 7, 1986) inorganic arsenicals have been classified in Group A (carcinogenic to humans).

A large number of toxicological studies are available on the oncogenicity of arsenic compounds. The most critical and persuasive evidence linking human cancer with exposure to inorganic arsenicals was derived from epidemiology studies. An excess mortality due to lung cancer from exposure to arsenic was demonstrated in several studies of smelter workers and among workers engaged in the production of arsenical pesticides. The increased mortality in these studies was related to occupational inhalation exposure to inorganic arsenicals.

A final risk model for occupational inhalation exposure was based on three studies of copper smelter workers and on an NCI series of statistical analyses of some of these same workers:

(a). Higgins, et al. (1982) conducted a followup study on smelter workers in Anaconda, Montana, who had previously been studied by Lee and Fraumeni in 1969. The Higgins study contains data on 1800 men, including all of the heavy exposure workers and 20% of the other workers from the Lee and Fraumeni study. Cumulative exposures were estimated and information on smoking habits was obtained for most of the cohorts. A statistically significant increase in the number of respiratory cancers was observed among non-smokers in the high exposure group. This study is summarized in the OHEA report, pp. 7-104 to 7-110.

b. Lee-Feldstein (1983) surveyed 8047 smelter workers at the same location as Higgins et al. in Anaconda, Montana. This large study followed mortality for up to 39 years among workers who had been employed for at least 12 months. Workers were categorized into heavy, medium, and light exposure groups and by length of employment. Detailed work exposure levels and work histories were available. At all exposure levels, there was a statistically significant number of excess respiratory cancers. This study is summarized in the OHEA report, pp 7-95 to 7-104.

c. Enterline and Marsh (1982) studied 2802 men who had worked at a Tacoma, Washington, smelter for a year or more between 1940 and 1964, with observations through 1976. Individual exposures to airborne arsenic were estimated using work histories and were correlated to levels of arsenic found in urine. A statistically significant increase in respiratory cancers was observed at the higher exposure levels studied. This study is summarized in the OHEA report, pp. 7-118 to 7-128.

d. Brown and Chu (1983 a, b, c) applied a multi-stage theory of carcinogenesis to the Anaconda smelter studies of Lee-Feldstein, taking into account exposure rate, durations of exposure, age at initial exposure, and time since cessation of exposure. Brown and Chu's analysis is described in the OHEA report, pp. 7-110 to 7-118.

The CAG used the epidemiological studies of Higgins, Lee-Feldstein, and Enterline and Marsh and the statistical analysis of Brown and Chu in developing its final unit risk estimate for inhalation oncogenic risk, as described in the OHEA report, pp. 7-130 to 7-135.

Other human epidemiology studies have demonstrated an association between skin cancer in non-occupational populations and high levels of arsenic in drinking water. Persons exposed to arsenicals in medicines have also been shown to be at risk. The Agency has prepared a risk model for oral exosure to inorganic arsenicals based on an epidemiology study of skin cancer in a section of Taiwan with high arsenic concentrations in well water (Tseng et al., 1968).

The Agency's Risk Assessment Forum, an Agency-wide task group charged with assessing risk issues, is currently reevaluating this risk model for exposure via the dermal and oral routes. Their report is expected to be issued in late 1986 or early 1987.

In contrast to the clear association between inorganic arsenicals and cancer in humans, arsenic carcinogenicity in test animals has not been observed in most studies. A few recent reports have noted positive results. Studies in species other than rats have generally shown negative findings. The OHEA document (pp. 7-77 to 7-87) summarizes 32 studies using animals, in which the majority of studies (25) were either negative or inconclusive. Given the extensive amount of information on human exposures, the Agency is not requiring additional oncogenicity animal studies.

(3). Mutagenicity

Providing support to the carcinogenic finding are results from numerous mutagenic and other gentoxic assays. The weight of evidence indicates that arsenate and arsenite can interact with DNA in mammalian somatic and gonadal cells and therefore may have the potential to cause heritable effects in humans.

Observed positive effects in various assays have included chromosome-breaking effects, interference with DNA repair mechanisms, direct toxicity to mammalian gonads, and positive effects in selected microbial test systems for mutagenicity.

The Agency concludes from the available data, that inorganic arsenicals, administered in either the pentavalent or trivalent form, may induce chromosomal aberrations in vitro. This effect has been shown in human fibroblast cells, Syrian hamster embryo cells, and human peripheral lymphocytes. Results for some studies are dose-related, and arsenites are more potent than arsenates in the induction of chromosomal aberrations in cultured mammalian cells. In addition, among lymphocytes cultured from exposed workers (or from patients undergoing treatment with medicinal arsenicals) there is suggestive evidence of chromosomal damage by arsenic *in vivo*. Furthermore, inorganic arsenic may potentiate the effects of chromosome-damaging agents (Sram, 1976; T.C. Lee, et al., 1986).

A dominant lethal test conducted by Sram and Bencko (1974), indicated that inorganic arsenic reached the germ cells (gonads) and produced mutagenic effects in mammals. Further, studies by Petres et al. (1970, 1977) suggest that human exposure to arsenic can cause chromosomal aberrations and aneuploidy in humans *in vivo*.

(4). Teratogenicity/Fetotoxicity

The potential of inorganic arsenic to produce teratogenic effects through parenteral exposure is established.

(a). Parenteral administration of sodium arsenate (+5) or sodium arsenite (+3) to experimental animals during pregnancy has produced gross malformations (terata) in the offspring. Increased mortality, increased resorptions, and decreased body weights of fetuses have also been observed in these studies.

(b). In contrast, oral (gavage) administration of sodium arsenate or arsenite to experimental animals has either failed to produce gross malformations in offspring or has produced only a slightly increased incidence and only at dosage levels that have also caused significant maternal mortality. NOELs could not be established for these studies. Oral administration of sodium arsenite to experimental animals yielded almost identical results to those for sodium arsenate although at somewhat lower dosage levels.

Intravenous and intraperitoneal administration are not typical of the exposure likely from pesticide use. The available oral studies do not fulfill Agency requirements, and do not demonstrate conclusively that inorganic arsenicals are teratogenic or fetotoxic by the oral route of exposure (except at levels also showing maternal effects). Therefore, the Agency is currently unable to assess the risks of teratogenicity/fetotoxicity likely from pesticide use of chromated and non-chromated arsenicals. Additional studies have been required to assess teratogenic risks. (See Special Data Call-In Notice on Wood Preservatives Containing inroganic Arsenicals, April 7, 1986).

(c). Arsenic can cross the placental barrier and has been incriminated in neonatal deaths (Gosselin et al, 1984). Human epidemiological studies have implicated arsenic as a teratogen. Increased spontaneous abortions and decreased mean birthweights of offspring were reported among female workers employed in a smelter in Sweden. These women were exposed not only to arsenic, however, but also to a variety of diverse chemicals in the smelter (OHEA, 1984).

(5). Reproductive effects

There are insufficient data to assess the effects of inorganic arsenicals upon reproductive functions. In light of the Agency's concern about possible teratogenic/fetotoxic effects of arsenicals, a reproduction study is required.

(6). Acute toxicity

The acute oral toxicity of inorganic arsenicals in humans has been well documented over centuries of use as a poison in homicides, suicides, and from accidental ingestion of drugs and pesticides. The pentavalent forms are less toxic than the trivalent ones; however, both forms are classified as Toxicity Category I (the Agency's highest acute toxicity category) and the symptoms of toxicity are the same. The reported oral toxicity of arsenic acid in rats is 48-100 mg/kg, however, the rat is a poor model for toxicity in man, since it binds arsenic in the body. Man appears to be more sensitive to arsenic poisoning on a dose per weight basis than the rat. Acute oral, dermal, and inhalation toxicity data are required. In addition eye and dermal irritation and dermal sensitization are required. All acute studies must be conducted on each manufacturing use product and end-use product.

(7). Neurotoxicity

Arsenic is known to cause neurotoxic effects in humans. The expression of severity of effects dependent upon the type and duration of exposure. Acute and subchronic exposures typically lead to peripheral neuropathy, distal muscle weakness and loss of sensation, which may progress to paralysis and crippling. Lower exposures and chronic exposures generally have a more gradual onset of similar symptoms.

(8). Other observed effects in humans

Other chronic and subchronic effects of inorganic arsenicals that have been observed in humans include:

- Skin toxicity, resulting in hyperpigmentation and disorders such as eczema, redness, keratosis, loss of nails, and swelling, which are reversible if exposure ceases.
- Toxicity to the blood system, resulting in blood dyscrasias of various forms, also is reversible if exposure ceases.
- Liver and kidney toxicity, with jaundice, degeneration of the tissues, and cirrhosis.
- Pulmonary system effects, perforation of the nasal septum, and tracheal and bronchial effects.

(9). Risks

The following risk estimates were extracted from the OHEA report on inorganic arsenic.

(a). The inhalation oncogenic risk of arsenic was based on epidemiological studies of copper smelter workers (Higgins et al., Lee-Feldstein, Enterline and Marsh, and three series of analyses by Brown and Chu). The final risk was estimated to be 4.1×10^{-3} for workers in pressure treatment plants based on an assumed exposure of 10 ug/m^3 inorganic arsenic levels in the air averaged over an 8 hour workday.

(b). The potential risks of skin cancer from dermal and oral (gastro-intestinal) exposure to arsenic were estimated using a risk equation based on the epidemiological study of skin cancer in more than 40,000 people in a section of Taiwan with high concentrations of arsenic in the well water (Tseng et al.). The Agency Risk Assessment Forum is currently reevaluating this risk model to be used for exposure via the oral and dermal routes. Their report is expected to be issued in late 1986 or early 1987.

However, based on this risk model the dermal risk estimates were:

i. 2.8×10^{-3} for brush on applications of arsenic,

ii. 6.2×10^{-3} for handling freshly treated wood and mixing dilute formulations, and

iii. 7.3×10^{-3} for bag emptying.

The oral (gastrointestinal) risk from sawing/ fabricating treated wood was estimated to be:

i. 3.1×10^{-4} (copper chromated arsenate) and

ii. 7.6×10^{-4} (ammoniacal chromated arsenate).

Regulatory measures (respirators, protective clothing, closed systems) required as part of the Special Review will reduce risks to the orders of 10^{-4} to 10^{-5}. This level of risk does not outweigh the benefits of continued registration of these products.

2. CHROMIUM

a. Risks

The toxicity of chromium has been discussed in detail in the Health Assessment Document for Chromium. This document includes a risk assessment for the carcinogenicity of chromium compounds and is the sole reference for the following discussion of chromium.

(1). Essentiality of Chromium and its Metabolism

Chromium exists in several valence states. Only the trivalent and hexavalent forms of chromium are biologically significant.

Trivalent chromium is an essential element in animals including humans. It plays a role in glucose and lipid metabolism. Chromium supplementation improves or normalizes glucose tolerance in diabetics, older people, and malnourished children. It has been suggested that chromium deficiency may be a basic factor in atherosclerosis. A deficiency of trivalent chromium apparently increases the toxicity of lead.

Although the exact level of chromium needed for good health is unknown, it is assumed that an average American intake of 0.05 to 0.2 mg/day is adequate.

Trivalent chromium transport in the blood is facilitated by specific binding proteins. Hexavalent chromium, on entering the blood stream, diffuses into the blood cells where reduction and binding to cellular components occurs. Absorbed trivalent and hexavalent chromium can be transported to a limited extent to the fetus in utero after exposures of the dams, although existing data do not allow quantitative estimations of fetal exposure. Chromium transported by the blood is distributed to other organs with greatest retention by the spleen, liver, and bone marrow. The major deposition site following inhalation exposure is the lungs, where chromium probably binds to the cellular material before absorption can occur.

Absorbed chromium is rapidly cleared from the blood while clearance from tissue is slower. Urinary excretion is the primary route of elimination accounting for somewhat over 50% of the eliminated chromium. Fecal excretion accounts for only 5% of the elimination from the blood. The remaining chromium is deposited into deep body compartments. Limited work on modeling the absorption and deposition of chromium indicates that adipose and muscle tissue retains chromium at a moderate level (approximately two weeks), while the liver and spleen store chromium for up to 12 months. Estimated half-lives for whole body chromium elimination are 22 days and 92 days for hexavalent chromium and trivalent chromium, respectively

(2). Oncogenicity

According to the Agency's draft Guidelines for Carcinogen Risk Assessment (49 FR 46294), and based on combined animal and human epidemiological data, hexavalent chromium is classified in Group A (carcinogenic to humans).

a. Epidemiological studies of chromate production facilities in the United States, Great Britain, West Germany, and Japan have all found an association between occupational exposure to chromium and lung cancer and are sufficient evidence of the carcinogenicity of chromium. Workers in the chromate production industry are exposed to both trivalent chromium (+3) and hexavalent chromium (+6) compounds. Most of the epidemiologic studies did not attempt to determine which chromium compounds were the etiologic agents.

The strength of the association of exposure in the chromate production industry with lung cancer is evidenced by the high lung cancer mortality ratios found in various studies, the consistency of results by different investigators in different countries, the dose-response found in several studies, and the specificity of the tumor site, the lung. The magnitude of the mortality ratios found in several studies (studies of three independent cohorts of chromate production workers found lung cancer mortality ratios of at least 9.5 or greater) lends strong support to the association between exposure in the chromate production industry with lung cancer.

The best data that can be used for estimating cancer risks due to exposure to chromium compounds are found in the study by Mancuso (1975). In that study, Mancuso reported age-specific lung cancer mortality data for chromate production workers in terms of total chromium exposure, which included exposure to both trivalent and hexavalent chromium compounds. Available data, discussed below, suggest that only hexavalent chromium compounds are carcinogenic.

b. Although increased risk of lung cancer has been associated with inhalation of chromium by workers in the chromium industry, as discussed below, it has proven difficult to demonstrate a carcinogenic response in the lungs of experimental animals.

Trivalent chromium compounds have not produced lung tumors after inhalation (in mice or rats), intratracheal implantation (in mice), or intrapleural implantation (in mice). Hexavalent chromium was not carcinogenic by inhalation (in mice or rats) or intratracheal instillation (in mice or rats). Some hexavalent chromium compounds did produce tumors following intrabronchial or intrapleural implantation (in rats); however, the number of animals (14) was small in the study of calcium chromate (Hueper and Payne, 1962). Furthermore, the report of Hueper (1961), where a number of hexavalent chromium compounds were reported to be carcinogenic, lacked detailed information. The combination of problems with these two studies make it difficult to evaluate the potential carcinogenicity of these compounds to rodent respiratory tissue.

For these reasons, studies of respiratory cancer in animals do not provide substantial confirmation of lung cancer. However, the limited data suggest that of the two valences, hexavalent chromium is more likely to be the etiologic agent in chromium-induced cancer.

Hexavalent chromium has produced implantation site tumors in rats following intramuscular implantation, while trivalent and metallic chromium compounds have not. The relevance of studies using intramuscular implantation to human risks following inhalation or oral exposure to chromium compounds is not clear; however, these animal studies again indicate that some hexavalent chromium compounds are likely to be the etiologic agent in human chromium-related cancer.

Trivalent chromium has been tested for carcinogenicity by the oral route in rats and mice with no significant increase in tumors in treated animals as compared with controls. These studies have not been reported in detail.

No additional oncogenicity data are required.

3. Mutagenicity

The valence state of chromium is an important factor in producing a mutagenic response in the Ames assay. Only hexavalent chromium has consistently demonstrated positive mutagenic activity in *Salmonella typhimurium* in the absence of metabolic activation. After metabolic activation, however, the chromium shows only marginal, if any, mutagenic activity. This suggests that the mammalian enzymes or cofactors in the activation system reduced hexavalent chromium to trivalent chromium. Although these studies show that hexavalent chromium compounds produce a positive response, they do not indicate whether hexavalent or trivalent chromium is the ultimate mutagen which interacts with the DNA of the cell.

Both trivalent chromium and hexavalent chromium have been demonstrated to interact with DNA in bacterial assays, and hexavalent chromium has inhibited DNA synthesis and increased unscheduled DNA synthesis in mammalian cells in culture.

In *in vitro* studies, both trivalent and hexavalent chromium have increased the infidelity of DNA replication. As observed with interaction with DNA, both valences of chromium have been demonstrated to produce clastogenic effects (chromosome breaking) in mammalian cells with hexavalent chromium being more active than trivalent chromium. The effects observed included a variety of chromosomal aberrations, sister chromatid exchange, and the appearance of micronuclei in polychromatic erythrocytes.

Increased chromosomal damage also has been observed in human lymphocytes cultured from subjects occupationally exposed to chromium.

For all the observed genotoxic effects, it has been suggested that trivalent chromium may be the predominant intracellular species as a result of the reduction of absorbed hexavalent chromium by cellular components.

No additional mutagenicity data are required.

4. Teratogenicity and Reproductive effects

Chromium has adversely affected fetal development and male reproduction in experimental animals.

Hamsters administered chromium trioxide intravenously on day 8 of gestation had an increased incidence of cleft palates in the young when examined on day 15 of gestation. The malformations were strain specific and associated with maternal toxicity.

Studies on the mouse indicated that while some skeletal effects were present, increased incidence of cleft palate or fetal death were not observed. While several of the studies reported fetal malformations only where maternal toxicity was also present, not all studies reported data on maternal effects, so definitive conclusions concerning the correlation between fetal and maternal effects cannot be made at this time.

Reproductive effects of chromium include testicular degeneration in rabbits receiving 2 mg/kg/day for 6 weeks of either trivalent or hexavalent chromium compounds by intraperitoneal injection. The trivalent chromium compound produced more severe effects in this study than did the hexavalent chromium compound (Behari et al., 1978).

The relevance of the observed effects in both the teratology and reproduction studies to effects observed after environmental exposure is questionable since the routes of exposure in these studies were not typical routes of exposure in humans. Therefore oral teratology and reproduction studies using a formulated chromated arsenical product are being required.

5. Acute toxicity

a. Trivalent chromium compounds have a very low order of toxicity when administered orally. Oral LD_{50} values for the rat have been reported as follows: chromic chloride, 1.87 g/kg; chromium acetate, 11.26 g/kg; chromium nitrate, 3.25 g/kg (Smyth et al., (1969). Kobayashi et al. (1976) have determined oral LD_{50} for chromium trioxide in mice and rats to be 135 to 177 mg/kg and 80 to 114 mg/kg, respectively, with death occurring between 3 to 35 hours. Symptomatology included diarrhea, cyanosis, tail necrosis, and gastric ulcer. Surviving animals showed increases in liver and testes weight without microscopic changes.

b. Hexavalent chromium is more acutely toxic than trivalent chromium. A primary effect of acute exposures is kidney failure. Oral administration of high doses results in gastric corrosion. The oral LD_{50} of sodium dichromate in humans has been reported as 50 mg/kg (NIOSH, 1979).

c. Numerous investigators have demonstrated that sensitization of laboratory animals (guinea pigs) can be produced by exposure to various chromium compounds, including both hexavalent and trivalent chromium.

Acute oral, dermal and inhalation toxicity data are required. In addition, eye and dermal irritation and dermal sensitization data are required. All acute studies must be conducted on each manufacturing-use product and end-use product.

6. Other observed effects in humans

Occupational exposure to chromium compounds, mainly through inhalation, causes dermatitis, penetrating ulcers on hands and forearms, perforation of nasal septum, and inflammation of the larnyx and liver. The dermatitis is probably due to an allergic response; persons sensitive to hexavalent chromium also respond to trivalent chromium. The ulcers are believed to be due to chromate ion and not metalic chromium. Chromic acid, and to a lesser extent, chromate, are presumably the causative agents in perforation of the nasal septum.

7. Risks

A number of epidemiologic studies have found an association between exposure to chromium compounds and lung cancer. The best data that can be used, however, for estimating cancer risks due to exposure to chormium compounds are found in the study by Mancuso (1975). That study reported age-specific lung cancer mortality data for chromate production workers in terms of total chromium exposure (i.e., exposure to both trivalent and hexavalent chromium combined).

As noted previously, available data suggest that only hexavalent chromium compounds are carcinogenic. Thus, a risk estimate based on total chromium exposure will underestimate the risk due to hexavalent chromium alone. In another study (Bourne and Yee, 1950), the ratio of trivalent to hexavalent chromium in airborne dust was determined in the plant's nine major departments. The ratio ranged from 1 to 3 in seven of the departments; was 6 for the lime and ash operation, and was as high as 52 for ore preparation. Therefore, excluding ore preparation, the maximum ratio of trivalent to hexavalent chromium is 6, and thus the underestimation of the risk would not be more than sevenfold.

The lifetime cancer unit risk calculated by the Agency from the Mancuso (1975) data was determined to be 1.2 x 10^{-2} based on a constant exposure to air containing lug/m^3 of total chromium.

Assuming that the ratio of trivalent to hexavalent chromium is 6:1, the Agency's risk estimate may underestimate the risk from hexavalent chromium by sevenfold. However, other factors such as use of 1949 hygiene data to determine worker exposure and implicit assumptions that the smoking habits of chromate workers are similar to those of the general white male population may result in overestimation of the risk by four times.

On balance, the estimate based on the Mancuso data is judged to be the best possible estimate of the risk from hexavalent chromium.

It is possible to estimate potential inhalation exposure of wood treatment workers to chromium, based on the ratio of chromium to arsenic in formulated products. This ratio has been calculated to be .96 or approximately 1:1.

If the bioavailability of chromium is similar to that of arsenic, the risk from the use of chromium in formulated wood preservative products will be the same order of magnitude as the risk from the use of arsenic in formulated wood preservative products. However, the relative bioavailability of these two constituents, administered together as formulated wood preservative products, is not fully known. The Agency is requiring data to determine the relative bioavailability.

C. OTHER SCIENCE ASSESSMENTS

1. Toxicity to fish and wildlife.

Data needed to fully assess the toxicity of chromated and non-chromated arsenicals to birds are not available. Based on avian dietary studies in mallard duck and bobwhite quail, copper chromated arsenicals can be characterized as at least slightly toxic to avian wildlife on a subacute basis. LC_{50}s of greater than 4640 ppm (CCA) were reported for both bobwhite quail and mallard duck.

The toxicity of copper chromated arsenicals to freshwater fish varies widely. The compound was reported to be highly toxic to rainbow trout (LC_{50} = .84 ppm) but only slightly toxic to bluegill sunfish (LC_{50} = 90.2ppm). Chromium LC_{50}s for freshwater fish have been shown to be in the range of 17 to 118 ppm. Additional studies will have to be submitted before the Agency can determine whether these values are reliable.

No evaluation of the acute toxicity of chromated arsenicals to freshwater aquatic invertebrates can be made at this time. Chromium LC_{50}s for Daphnia have been reported to be approximately 0.05 ppm.

2. Endangered species

A hazard assessment to endangered species can not be made until the aquatic availablilty studies required under this standard are submitted. These studies will indicate whether or not the amount of [Cr], [As], and additional ions which leach out of treated wood into the soil and water is high enough to pose a threat to endangered species.

3. Environmental Fate

The Agency lacks data to characterize the environmental fate of chromium and arsenic formulated as chromated arsenicals. The Agency is requiring studies to determine the availability of chromium and arsenic from treated wood to both soil and aquatic media. Results of these studies will determine whether additional environmental fate data will be required.

3. Benefits

The application of wood preservative chemicals protects wood from attack by fungi, insects, bacteria, or marine borers. In most cases the life expectancy of treated wood is five or more times that of untreated wood.

The following is a summary of the extensive benefits analysis contained in the PD 4 for Wood Preservatives. Because chromium is often an additional active ingredient of inorganic arsenical wood preservatives the benefits from the use of chromium approximate those of the inorganic arsenical wood preservatives discussed below. Arsenical wood preservatives have three major uses and several other wood uses as described below.

a. Lumber, Timber, and Plywood

In 1978 more than 70% of the total treated lumber, timber and plywood was treated with inorganic arsenicals. Inorganic arsenical treated wood is clean, odorless, paintable, easy to handle, harmless to plants and more durable than other treated wood. Uses includ patios, decks, playground equipment, cooling towers, greenhouses, horticultural nurseries, and all-weather wood foundations. The two other major wood preservatives, pentachlorophenol and creosote, have limited uses for lumber, timber and plywood due to odor, objectionable vapors, and oily surfaces which can not be painted.

Because of the wide variety of uses for treated lumber, timber, and plywood, the Agency could not quantify the anticipated economic impact if all three wood preservatives considered in the special review had been cancelled for this use. Non-wood materials such as plastic, steel, or concrete would be substituted for treated wood and would likely cost more than wood. There would be a major adverse economic impact if the registrations of inorganic arsenicals were cancelled because pentachlorophenol and creosote treated lumber, timber, and plywood are not generally acceptable alternatives to lumber, timber, and plywood treated with inorganic arsenicals.

b. Fence Posts

In 1978, about 25% of fence posts were treated with inorganic arsenicals. If the inorganic arsenicals were cancelled, the impact would be a cost increase of $4.0 to $4.5 million annually for treated wood posts depending on which alternative (creosote or pentachlorophenol) is chosen. If all three wood preservatives were cancelled, steel or concrete posts would be the most likely alternative for fence posts. Although steel posts are priced competitively with treated wood posts, farmers' preference for treated wood posts indicates that they are superior to metal posts in terms of cost or performance (USDA, 1980, p. 325). Concrete posts would be more expensive than steel and would not be substituted in most farm situations.

c. Wooden Poles

In 1978, approximately 6% of wooden poles were treated with inorganic arsenicals. With one exception, there are no viable chemical alternatives for the three major wood preservatives used for treating poles. Copper naphthenate can substitute for the three major wood preservative chemicals for treating poles. However, due to the wood becoming brittle, the uses of copper naphthenate treated poles is limited. Non-wood alternatives for treatment of poles include the use of concrete and steel as pole construction materials. Another alternative (for telephone and electric poles) would be to install underground distribution and transmission lines in urban areas or in new subdivisions.

If inorganic arsenicals were cancelled for wooden poles, there would be an additional cost of $1.9 million for the first year and an additional cost of $17.8 to $32.8 million for each subsequent year. If all three major wood preservatives were cancelled for poles, the most likely substitutes would be concrete and steel. Under this scenario there would be large cost increases ranging from $1.3 to $2.1 billion annually depending on the alternative chosen.

IV. REGULATORY DETERMINATIONS

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on chromium and arsenic, the Agency has made the following determinations:

1. The Agency will not, at this time, initiate a Special Review [40 CFR Part 154 (previously 40 CFR 162.11)] on the wood preservative uses of inorganic arsenicals or chromium.

   Rationale: Inorganic arsenicals were placed in Special Review by the Agency in October, 1978 due to suspected oncogenic, mutagenic, and teratogenic/fetotoxic effects. The Special Review resulted in the Agency's determination that inorganic arsenicals are mutagenic. The Special Review also resulted in the classification of inorganic arsenicals as Group A oncogens (See Preliminary Risk Assessment, and the Agency's Draft Guidelines for Carcinogenic Risk Assessment, January 7, 1986). The Agency further determined that requirements for protective measures and restrictions would reduce exposure and risk to levels that are outweighed by the benefits of these compounds. The Special Review also resulted in the determination that teratogenicity data for inorganic arsenic are inadequate and replacement studies were required through a Data Call-In letter dated April 7, 1986. Once the appropriate data are received, the Agency can reassess the potential for inorganic arsenicals to result in teratogenic effects.

   There is an established association between hexavalent chromium and carcinogenicity in humans. Chromium has been classified as a Group A oncogen and has also been shown to be mutagenic in short term assays. Both the potency of, and the exposure to chromium from wood preserving uses, are expected to approximate those for inorganic arsenicals and the risks from each are of the same order of magnitude. Further, the protective measures imposed as a result of the Special Review on workers using inorganic arsenical wood preservatives (most of which contain chromium) are expected to reduce exposure from chromium as well and result in reductions in risk of the same order of magnitude. Therefore, the Agency is not, at this time, placing chromium into Special Review.

2. The Agency is maintaining the Restricted Use classification which was imposed as a result of the Special Review. The Restricted Use classification applies to all wood preservative uses of chromated and non-chromated arsenicals except the commercial construction brush-on use.

   Rationale: Inorganic arsenicals and chromium have been demonstrated to cause carcinogenicity in humans by the inhalation route of exposure. The Agency believes that, to minimize the risks to users of chromated arsenicals, use should be limited to persons who have been trained in proper use procedures and exposure reduction measures.

3. The Agency is maintaining all other measures and restrictions resulting from the Special Review as well.

   Rationale: Among the other requirements imposed as a result of the Special Review were protective clothing and equipment requirements; the requirement to limit visible surface residues on treated wood; the requirement for the use of closed systems for emptying and mixing powder formulations; and the requirement to use respirators unless monitoring shows arsenic air levels to be below 10ug/m3 (See Section IV D, Required Labeling). These measures and restrictions are necessary to reduce exposure of persons who are treating wood with inorganic arsenicals.

4. The Agency is not, at this time, placing any regulatory requirements or restrictions on use of the treated wood itself.

   Rationale: Risk from exposure to treated wood itself is expected to be less significant than that resulting from exposure to the wood preservative chemicals prior to application. This is due to the fact that the wood preservative chemicals are bound to the wood and have only limited availability from the wood after treatment.

   Nonetheless, the wood preserving industry has instituted a voluntary consumer awareness program designed to inform users of treated wood of proper uses and handling precautions (See Appendix II). If the Agency determines, in the future, that risks from use of treated wood are higher than believed, regulatory requirements or restrictions will be considered.

5. The Agency is requiring an air monitoring study to determine the potential exposure to chromium under conditions found within wood treating plants. The study must also determine the relative chromium/arsenic ratio found in the air samples.

2. The Agency is maintaining the Restricted Use classification which was imposed as a result of the Special Review. The Restricted Use classification applies to all wood preservative uses of chromated and non-chromated arsenicals except the commercial construction brush-on use.

   Rationale: Inorganic arsenicals and chromium have been demonstrated to cause carcinogenicity in humans by the inhalation route of exposure. The Agency believes that, to minimize the risks to users of chromated arsenicals, use should be limited to persons who have been trained in proper use procedures and exposure reduction measures. The Agency decided not to require the commercial brush on uses to be restricted to certified applicators in favor of labeling which would require use only in commercial applications for cut ends of pressure treated wood. The Special Review Final determination, referred to on page 5 of this document, provides additional details.

3. The Agency is maintaining all other measures and restrictions resulting from the Special Review as well.

   Rationale: Among the other requirements imposed as a result of the Special Review were protective clothing and equipment requirements; the requirement to limit visible surface residues on treated wood; the requirement for the use of closed systems for emptying and mixing powder formulations; and the requirement to use respirators unless monitoring shows arsenic air levels to be below 10ug/m3 (See Section IV D, Required Labeling). These measures and restrictions are necessary to reduce exposure of persons who are treating wood with inorganic arsenicals.

4. The Agency is not, at this time, placing any regulatory requirements or restrictions on use of the treated wood itself.

   Rationale: Risk from exposure to treated wood itself is expected to be less significant than that resulting from exposure to the wood preservative chemicals prior to application. This is due to the fact that the wood preservative chemicals are bound to the wood and have only limited availability from the wood after treatment.

   Nonetheless, as part of a settlement agreement with the Agency, the wood preserving industry has instituted a voluntary consumer awareness program designed to inform users of treated wood of proper uses and handling precautions (See Appendix II). If the Agency determines, in the future, that risks from use of treated wood are higher than believed, regulatory requirements or restrictions will be considered.

5. The Agency is requiring an air monitoring study to determine the potential exposure to chromium under conditions found within wood treating plants. The study must also determine the relative chromium/arsenic ratio found in the air samples.

   Rationale: Due to the oncogenic potential and other toxicological concerns of the various component of the chromated and non-chromated inorganic arsenicals, in-plant, on-site measurements of the ambient airborne levels of arsenic and chromium from treating mixtures is required. These data will allow the Agency to determine whether the potential exposure to chromium in wood treating plants poses more significant concern than that previously described in this document due to exposure to arsenic. These data may also allow the Agency to calculate airborne chromium levels based on the arsenic levels found from the ongoing monitoring required as a result of the Special Review, thus potentially alleviating the need for future chromium monitoring.

6. The Agency is requiring teratology and reproduction studies using a representative chromated arsenical formulation unless the required metabolism study demonstrates that blood levels of chromium and arsenic, after exposure to the formulated product, are not increased above background levels.

   Rationale: Current information regarding the bioavailability of chromium and arsenic after exposure to formulated chromated arsenical wood preservatives is inadequate. The current assumption is that chromium blood levels do not increase beyond background levels. The metabolism data will allow the Agency to determine whether this assumption is correct. The metabolism, teratology, and reproduction studies must be conducted using a test species other than the rat since the rat is known to be anomalous to humans with respect to metabolism of arsenic.

7. The Agency is deferring a decision regarding the need for many of the environmental fate studies normally required. The Agency will determine the need for these environmental fate studies after special availability studies (in aqueous and soil media) for end use products are submitted and reviewed.

   Rationale: There is inadequate information on the amount of the formulated product which actually is available to aqueous or soil media from treated wood. Therefore, the Agency is requiring testing to determine the quantity, form, and valence of each component of the chromated and non-chromated arsenicals which is available to these media from commercially treated wood. If these studies indicate that the concentration of arsenic, chromium, or the additional ions combined together in the formulated product, is high enough to cause concern, the Agency may require additional environmental fate data for arsenic, chromium, or the additional ions.

8. Chronic aquatic testing may be required depending on the outcome of (1) acute and subchronic aquatic organism testing, (2) aqueous and soil availability studies, and (3) the Agency's resultant hazard assessment.

   Rationale: The uses of treated wood (as pilings and in the construction of boat docks and bridges) may allow a continuous release of chromium and arsenic into aquatic environments. As a result, aquatic organisms are likely to be exposed to chromium and arsenic ions. The amount of release over time to the aquatic environment from these uses is not yet known. If acute, subchronic, and availability data indicate that exposure may be significant over extended periods of time, data may be required to determine whether there are long term effects to aquatic organisms.

9. The Agency cannot assess the hazard to endangered species from use of treated wood at this time.

   Rationale: In order to determine potential exposure to endangered species, the aquatic organism data and special availability studies discussed in regulatory positions 7 and 8 in addition to acute avian studies must be submitted and reviewed. A full hazard assessment will be conducted when these data are received.

10. In addition to the product chemistry data traditionally required for manufacturing-use and technical products, the Agency is requiring that the source and description of arsenic, chromium, and other active ingredients in the formulated end-use products be submitted to the Agency.

    Rationale: Arsenic and chromium are commodity chemicals with many non-pesticidal uses. Frequently, active ingredients incorporated into formulated products are not registered for manufacturing-use and the chemical characteristics of each product are unknown. These data will allow the Agency to determine these characteristics for the individual products.

11. While the data gaps are being filled, currently registered manufacturing use products (MPs) and end-use products (EPs) containing as sole actives or multiple actives, the chemicals subject to this Registration Standard, may be sold, distributed, formulated and used, subject to the terms and conditins secified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

    Rationale: Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, authorizes the Administrator to cancel a pesticide registration if he determines that the pesticide will cause unreasonable adverse effects on the environmentl. Based on available data, the Administrator has not made such a determination as to chromated and non-chromated arsenical wood preservatives. The Administrator has authority under FIFRA sections 3(c)(2)(B) and 3(c)(7)) to require registrants and applicants for registration to provide data needed to support new or continuing registrations.

    Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated and the Agency will determine if the data will affect the registration of chromated and non-chromated arsenical wood preservatives.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain arsenic or chromium and arsenic as the active ingredient(s), bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain either a salt of chromium or a salt of arsenic and must be sold for the purpose of formulating into an arsenical or chromated arsenical wood preservative pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

To be registered or reregistered under this Standard, end-use products (EPs) must contain a mixture of salts that contain either arsenic or both arsenic and chromium, and must be labeled for wood preservation only.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacturing-use, and end-use products containing arsenic or both arsenic and chromium provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products, and end-use products may be labeled only for the commodities listed below. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, non-food uses on wood

D. REQUIRED LABELING

All manufacturing-use products, formulation intermediates, and end-use products must bear appropriate labeling as specified below, and in 40 CFR 162.10 and PR Notices 83-2, 83-3 (as appropriate). Appendix II contains information on label requirements.

Wood preservative pesticide product containing arsenic or both chromium and arsenic as active ingredient(s) may not be released for shipment by the registrant after October 31, 1987 unless the product bears an amended label which complies with the requirements of this Standard.

Wood preservative pesticide product containing arsenic or both chromium and arsenic as active ingredient(s) may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after October 31, 1988 unless the product bears an amended label which complies with the requirements of this Standard.

The following information must appear on the labeling:

1. Manufacturing Use Products

a. Ingredient Statement

The ingredient statement for manufacturing use products must list the percentage of each component used in the formulation of the chromated or non-chromated arsenical which contributes to the pesticidal activity of the product.

b. Use Pattern Statement

All manufacturing-use products must state that they are intended for formulation into end-use products for wood preservation.

c. Ecological Hazard Statement

All manufacturing-use products must bear the following ecological hazard statement:

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional office of EPA."

2. All End-Use Products: The following statements must appear on the labeling of all end use products subject to this Registration Standard.

a. Ingredient Statement

The ingredient statement for end-use products must list the percentage of each component used in the formulation of the chromated or non-chromated arsenical which contributes to the pesticidal activity of the product.

b. Use Pattern Statement

All end-use products must be labeled for wood preservation. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in the Data Appendices for that use pattern.

3. End Use Products Labeled for Pressure Treatment of Wood: In addition to the statement in (2) above, the following statements must appear on end use products subject to this registration standard and which are labeled for pressure treatment of wood

a. Restricted Use Statement

"RESTRICTED USE PESTICIDE"

"For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification.

Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors). "

b. Personal Protective Equipment Statement

"Individuals who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators (MSHA/NIOSH-approved for inorganic arsenic) if the level of inorganic arsenic in the plant is unknown or exeeds 10 micrograms per cubic meter of air (10ug/m^3) averaged over an 8-hour work period."

"Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations."

"Individuals in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m^3) averaged over an 8-hour work period.

"Note to user - Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene."

c. Monitoring

"Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instructions on the attached labeling material."

d. General Work Practice Statements

"Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the wood treatment formulation (e.g., manually opening/closing cylinder doors, moving trams out of cylinders, mixing chemicals, and handling freshly treated wood)."

"Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products or using restrooms."

e. Disposal

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

f. Ecological Hazard Statement

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional office of the EPA."

g. Visible Residue Statement

"Processes used to apply inorganic arsenical formulations shall leave no visible surface deposits on the wood, as defined by AWPA Standard C-1 and AWPB Standards LP2 and LP22. (Visible surface deposits means a surface residue or crystallization on the treated wood. Small isolated or infrequent spots of chemical on otherwise clean wood shall be allowed.) "

h. Permissible Exposure Limit (PEL) Monitoring Program

The following must be included as labeling, with each end-use product labeled for pressure treatement of wood:

"Implementation of the Permissible Exposure Limit (PEL) Monitoring Program"

"Each arsenical wood treatment plant employer shall require all employees potentially exposed to airborne inorganic arsenic to wear properly fitting, well maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic for the entire period that the employees are in the treatment application work area or engaged in any activity associated with the treatment process. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program. This requirement became effective on July 10, 1986. Any plant which begins operations after April 10, 1986 will have 3 months from the date of initial operation to implement this program."

"All wood treatment plant employers who elect to implement the PEL monitoring program must determine the current levels of airborne arsenic, averaged over an 8-hour period, to which their employees are exposed. Monitoring data must be obtained in the same manner as described below under 'Monitoring and Measurements Procedures'."

"If the initial or subsequent monitoring demonstrates that airborne inorganic arsenic in a work area is greater than 10ug/m^3, all employees working in that area are required to wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic. If in subsequent monitoring, at least two consecutive measurements taken at least 7 days apart, the inorganic arsenic levels are below 10ug/m^3, employees in those areas may discontinue wearing the respirators except as discussed in the "PEL checklist" below. However, if the employee exposure is below 10ug/m^3 but above 5ug/m^3, the employer shall repeat monitoring at least every 6 months until at least two consecutive measurement, taken at least 7 days apart, are below 5ug/m^3. The employer may then discontinue monitoring except as discussed in the 'PEL Checklist' below."

"If the monitoring reveals employees are exposed to airborne arsenic levels below 5ug/m^3, monitoring need not be repeated except as discussed in the 'PEL Checklist' below."

"PEL CHECKLIST"

"In all cases where there has been a change in production, process, control, or employee handling procedures, or if any events in the PEL Checklist occurred, or if, for any other reasons an employer should suspect new or additional airborne inorganic arsenic, additional monitoring that complies with the requirements for initial monitoring shall be completed. Responses to the Checklist will become part of the monitoring records. Monitoring is required within 3 months if any of the following events/questions on the checklist can be answered in the affirmative with respect to any events which may have occurred since the last monitoring report submitted to the Agency."

"1. After the wood has been treated, have you changed from hand stacking to mechanical stacking or from mechanical stacking to hand stacking? If yes, when?"

"2. Has your production capacity increased significantly? If yes, when?"

"3. Have you changed from a ready-to-use or dilute concentrate to a mix-it-yourself formulation? Has the proportional amount of arsenic in the solution increased, e.g., have you shifted from CCA Type A or C to type B? If yes, when?"

"4. Has a significant (i.e., reportable under the Comprehensive Environmental Response, Compensation, and Liabililty Act of 1980 (Superfund), 42 U.S.C. 9601 et seq.), spill occurred? If yes, when?"

"5. Is treated wood being retained on the drip pad for less time? If yes, when?"

"6. Have there been any other production, process, control or employee handling procedure changes which could result in new or additional airborne inorganic arsenic? Identify change, and when it occurred."

"MONITORING AND MEASUREMENT PROCEDURES"

"The Employer shall collect personal air samples, including at least one sample which is adequate to represent typical conditions for a full work shift (at least 7 hours) for each job classification in each work area. Sampling should be done using a personal sampling pump calibrated at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size membrane filters (37mm diameter). The method of sampling analysis should have an accuracy of not less than + or - 25 percent (with a confidence limit of 95 percent) for 10 micrograms per cubic meter of air (10ug/m^3), and + or - 35 percent (with a confidence limit of 95 percent) for concentrations of inorganic arsenic between 5 and 10ug/m^3."

"Monitoring may be conducted through a request made to the Occupational Safety and Health Administration (OSHA) for monitoring assistance, which may be provided free of charge under the terms of the OSHA consultation program as provided under section 7(c)(1) of the OSHA Act, or by employees or contractors of the employer's choosing."

"The Environmental Protection Agency (EPA) may direct that remonitoring take place at statistically selected establishments to assure that the Checklist is effective in identifying events which increase airborne arsenic. Selected employers will be notified by EPA/State enforcement representatives. The employer will be responsible for obtaining current air monitoring data within the time specified in the remonitoring notification and for submitting these data and reports to the EPA as described below."

DATA SUBMISSION AND CERTIFICATION

"The employer shall establish and maintain accurate records which include responses to the PEL Checklist and all monitoring reports. The annual records or copies thereof shall be submitted to the U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances Office of Compliance Monitoring (EN-342), 401 M St., SW, Washington, D.C. 20460. All records submitted will be certified by the employer as accurate and in compliance with all calibration, analytical and sampling requirements outlined in this program. If the employer received assistance from an OSHA 7(C)(1) consultant, that consultant's report to the employer will be an acceptable record of calibration, analysis, and monitoring requiring no additional certification."

4. All End Use Powder Formulations Labeled For Pressure Treatment of Wood: In addition to those statements in D(2) and (3) above, the following statement must appear on all powder formulations labeled for pressure treatement of wood:

"A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment, except that the release of incidental amounts of chemical during equipment loading and periodic clean-out or maintenance operations shall not be deemed a breach of containment."

5. End Use Products Labeled for Brush on Treatment: In addition to the statements in D(2) above, all end use products labeled for brush on treatment must bear the following statements:

a. Protective Clothing

"Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood). "

"Applicators must wear disposable coveralls (e.g., vinyl, or polyethylene) or other similar impermeable clothing during the application process where dermal contact is expected."

"Protective clothing must be changed when it shows obvious signs of contamination. Launder non-disposable protective clothing separately from other household laundry. Dispose of worn-out protective clothing in a manner approved for pesticide disposal and in accordance with state and federal regulations."

b. General Work Practice Statement

"Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the wood treatment formulation."

"Wash thoroughly after skin contact and before eating, drinking, use of tobacco products, or using restrooms."

c. Disposal

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

d. Ecological Hazard Statement

"This product is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of waste."

e. Use Pattern Statement

"For application to the cut ends of pressure-treated wood only. Do not dilute or mix with other products."

"For commercial construction use only. Not for household use."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing chromated or or non-chromated arsenicals as the sole active ingredient or as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard.

Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products.

B. End use products containing chromated or non-chromated arsenicals as the sole active ingredient or as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

5. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing (name of pesticide) as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form   ), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing (name of pesticide) alone or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing (name of pesticide) either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Henry Jacoby PM 21
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICAL TECHNICAL PRODUCTS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	No	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENCAL TECHNICAL PRODUCTS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	No	N/A	Yes	6 Months
63-9 - Vapor Pressure	PAI	All	No	N/A	Yes	6 Months
63-10 - Dissociation constant	PAI	All	No	N/A	Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No	N/A	Yes	6 Months
63-12 - pH	TGAI	All	No	N/A	Yes	6 Months
63-13 - Storage Stability	TGAI	All	No	N/A	Yes	15 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	No	N/A	No	

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

TABLE A
GENERIC DATA REQUIREMENTS FOR [X] of CHROMATED AND NON-CHROMATED ARSENICALS ([X]CrAs and [X]As)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	H	No		Reserved	
164-2 - Aquatic (Sediment)	TEP	H	No		Reserved	
164-3 - Forestry	TEP	H	No		No[2]	
164-4 - Combination and Tank Mixes	TEP	H	No		Reserved[4]	
164-5 - Soil, Long-term	TEP	H	No		No[2]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	H	No		No[2]	
165-2 - Rotational Crops (Field)	TEP	H	No		No[2]	
165-3 - Irrigated Crops	TEP	H	No		Reserved	
165-4 - In Fish	TGAI or PAIRA	H	No		Reserved	
165-5 - In Aquatic Non-Target Organisms	TEP	H	No		Reserved	

TABLE A
GENERIC DATA REQUIREMENTS FOR Cr of CHROMATED ARSENICALS ([X]CrAs)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	H	No		Reserved	
Photodegradation						
161-2 - In water	TGAI or PAIRA	H	No		Reserved	
161-3 - On soil	TGAI or PAIRA	H	No		Reserved	
161-4 - In Air	TGAI or PAIRA	H	No		Reserved	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	H	No		Reserved	
162-2 - Anaerobic Soil	TGAI or PAIRA	H	No		No[2/]	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	H	No		Reserved	
162-4 - Aerobic Aquatic	TGAI or PAIRA	H	No		Reserved	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	H	No		Reserved	
163-2 - Volatility (Lab)	TEP	H	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	H	No		Reserved[3/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR Cr of CHROMATED ARSENICALS ([X]CrAs)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	H	No		Reserved	
164-2 - Aquatic (Sediment)	TEP	H	No		Reserved	
164-3 - Forestry	TEP	H	No		No[2/]	
164-4 - Combination and Tank Mixes	TEP	H	No		Reserved[4/]	
164-5 - Soil, Long-term	TEP	H	No		No[2/]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	H	No		No[2/]	
165-2 - Rotational Crops (Field)	TEP	H	No		No[2/]	
165-3 - Irrigated Crops	TEP	H	No		Reserved	
165-4 - In Fish	TGAI or PAIRA	H	No		Reserved	
165-5 - In Aquatic Non-Target Organisms	TEP	H	No		Reserved	

TABLE A
GENERIC DATA REQUIREMENTS FOR As of CHROMATED AND NON-CHROMATED ARSENICALS ([X]CrAs and [X]As)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	H	No		Reserved	
Photodegradation						
161-2 - In water	TGAI or PAIRA	H	No		Reserved	
161-3 - On soil	TGAI or PAIRA	H	No		Reserved	
161-4 - In Air	TGAI or PAIRA	H	No		Reserved	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or AEP 5/	H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	H	No		No 2/	
162-3 - Anaerobic Aquatic	TGAI or AEP 5/	H	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or AEP 5/	H	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	H	No		Reserved	
163-2 - Volatility (Lab)	TEP	H	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	H	No		Reserved 3/	

TABLE A

GENERIC DATA REQUIREMENTS FOR As of CHROMATED AND NON-CHROMATED ARSENICALS ([X]CrAs and [X]As)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	H	No		Reserved	
164-2 - Aquatic (Sediment)	TEP	H	No		Reserved	
164-3 - Forestry	TEP	H	No		No[2/]	
164-4 - Combination and Tank Mixes	TEP	H	No		Reserved[4/]	
164-5 - Soil, Long-term	TEP	H	No		No[2/]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	H	No		No[2/]	
165-2 - Rotational Crops (Field)	TEP	H	No		No[2/]	
165-3 - Irrigated Crops	TEP	H	No		Reserved	
165-4 - In Fish	TGAI or PAIRA	H	No		Reserved	
165-5 - In Aquatic Non-Target Organisms	TEP	H	No		Reserved	

TABLE A

GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS ([X]CrAs and [X]As)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
SPECIAL STUDIES -LAB:						
Availability Studies						
Aqueous Availability	AEP 5/	H	Partially	GS-0647-001	Yes 1/	12 Months
Soil Availability	AEP 5/	H	No		Yes 1/	12 Months
SPECIAL STUDIES - EXPOSURE						
Ambient Air Availability Studies						
[X]	TEP	H	No		Reserved 6/	
Total Cr	TEP	H	No		Yes 7/	12 Months
Speciated Cr	TEP	H	No		Reserved 8/	
As	TEP	H	No		Yes 9/	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS ([X]CrAs and [X]As)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	H	No		Reserved	
132-2 - Soil Dissipation	TEP	H	No		Reserved	
133-3 - Dermal Exposure	TEP	H	No		Reserved	
133-4 - Inhalation Exposure	TEP	H	No		Reserved	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

§158.130 Environmental Fate

1/ For all applied end-use products, tests are to be made after product is applied with normal processing techniques and allowed to cure in usual manner. Products to be tested will be the treated wood or wood products as availabe in the marketplace.

2/ No use pattern identified by this Standard which requires this data.

3/ Field volatility study reserved pending the result of the laboratory volatility study.

4/ Some chromated arsenical wood preservative products may be formulated as tank mixes. Additional data may be required on these mixes at a later date.

5/ AEP = applied end-use product; tests must determine the availability of Cr and As to aqueous and soil media after application of a formulated end-use product to wood.

6/ Study reserved pending results of volatility and availability studies.

7/ Exposure study required to determine the levels of airborne total Cr and Cr/As ratio in air of [X]CrAs and [X]As treating plants. An acceptable speciated Cr in air study may be substituted for the total Cr air availability study. Protocols should be submitted for review prior to the initiation of this study and be consistent with Subdivision U of the Pesticide Exposure Guidelines.

8/ Study is reserved pending the results of the total Cr in air study.

9/ Monitoring of As in air of treating plants as required under the Federal Register Notice (51 FR 1334) January 10, 1986.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	B	N/A		No[1]	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	B	N/A		No[1]	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	B	N/A		No[1]	
81-7 - Delayed Neurotoxicity - Hen	TGAI	B	N/A		No[1]	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:						
- Rodent, and	TGAI	B	Yes	00159870, GS-0647-02	No	
- Non-rodent (Dog)	TGAI	B	Yes	00159870, GS-0647-02	No	
82-2 - 21-Day Dermal - Rabbit	TGAI	B	Yes	00120843	No	
82-3 - 90-Day Dermal - Rabbit	TGAI	N/A			N/A	
82-4 - 90-Day Inhalation: - Rat	TGAI	N/A			N/A	
82-5 - 90-Day Neurotoxicity:						
- Hen	TGAI	B	No		No	
-Mammal	TGAI	B	Yes	00159870	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI	B	Yes	00159870, GS-0647-02	No	
- Non-rodent (Dog)	TGAI	B	Yes	00159870, GS-0647-02	No	
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI	B	Yes	00159870, GS-0647-02	No	
- Mouse (preferred)	TGAI	B	Yes	00159870, GS-0647-02	No	
83-3 - Teratogenicity - 2 species:						
- Rodent other than rat	TGAI	B	No		[As] Yes 2/ 3/ [Cr] Yes	 15 Months
- Rabbit	TGAI	B	No		[As] Yes 2/ 3/ [Cr] Yes	 15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	B	No		[As] Yes 4/ 4/ [Cr] Yes	39 Months 39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	B	Yes	GS-0647-02	No	
84-2 - Structural Chromosomal Aberration	TGAI	B	Yes	GS-0647-02	No	
84-4 - Other Genotoxic Effects	TGAI	B	Yes	GS-0647-02	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	TEP	B	Partially	GS-0647-02	Yes[5/]	24 Months
85-2 - Dermal Penetration	Choice	B	No		No	
86-1 - Domestic Animal Safety	Choice	B	Yes	GS-0647-02	No	

§158.135 Toxicology - Continued

1/ There is no technical grade active ingredient for the chromated arsenicals. The acute toxicity of arsenic and chromium is thoroughly documented in public literature and acute toxicity tests on the separate ions are not necessary. However, acute toxicity tests are required on all formulated products (see tables B and C).

2/ Teratogenicity study on arsenic to be submitted by July 1987 as per the Special Review Data Call-In letter dated April 7, 1986.

3/ Test material should be a formulated chromated arsenical product.

4/ Test material should be a formulated chromated arsenical product. This test will satisfy the reproduction study requirement for both [As] and [Cr].

5/ The Agency requires a repeated-dose metabolism study on a rodent other than the rat. The Agency should be consulted regarding the test material. The preferred test material is a formulated chromated arsenical. The protocol must include determination of blood levels of chromium and arsenic during treatment.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TEP	B, D, H	No		Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity - Upland Game Bird, and - Waterfowl	TEP	B, D, H	Partially	000104061 000106113	Yes[2]	9 Months
71-3 - Wild Mammal Toxicity	TEP	B, D	No		No[3]	
71-4 - Avian Reproduction - Upland Game Bird, and - Waterfowl	TEP	B	No		No[4]	
71-5 - Simulated Field Testing - Mammals, and - Birds	TEP	B	No		No[4]	
- Actual Field Testing - Mammals, and - Birds	TEP	B	No		No[4]	

TABLE A
GENERIC DATA REQUIREMENTS CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and	TEP	B, D, H	Partial	000099363	Yes[5/]	9 Months
- Warmwater Fish Species						9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TEP	B, D, H	No		Yes	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TEP	D	No		Yes[6/]	
- Fish						12 Months
- Mollusk						12 Months
- Shrimp						12 Months
72-4 - Fish Early Life Stage, and	TEP	D	No		Yes[7/]	15 Months
- Aquatic Invertebrate Life-Cycle						15 Months
72-5 - Fish - Life-Cycle	TEP	D	No		Reserved[8/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TEP	D	No		Reserved[8]	
- Crustacean						
- Fish						
- Insect Nymph						
- Mollusk						
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	D	No		Reserved[8]	
- Actual Field Testing -Aquatic Organisms						

TABLE A
GENERIC DATA REQUIREMENTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

§158.145 Wildlife and Aquatic Organisms - Continued

1/ There is no actual technical grade of the active ingredient for chromated arsenicals. Therefore a typical end-use product should be used as the test material.

2/ Both studies cited may be upgraded if the percent active ingredient is clarified. Study assumed 100% active ingredient; percent a.i. used must be documented.

3/ Not usually required unless there is a unique exposure situation for feral animals. Toxicology acute testing suffices.

4/ Not required because exposure to avian and mammal species is expected to be minimal.

5/ Study may be upgraded if dissolved oxygen measurements and pH values, as required by the Pesticide Assessment Guidelines; Subdivision E, are submitted.

6/ Required to support use of treated wood in estuarine/marine environments.

7/ Required because of expected continuous exposure of aquatic organisms through leaching of chromated arsenicals from submersed wood.

a) A flow-through system should not be used. Rather, two tanks, a test tank and a "leaching tank" should be set up and the water should circulate between the two. The first tank, containing the test organisms, should be set up as in a normal study but with a provision for recirculation. The second tank should be large, at least 200 gallons, so that waste products may be diluted to maintain good water quality. Data should be submitted showing that materials used to construct the tanks do not absorb or adsorb the ions of interest to a significant extent. In this second tank, the CCA-treated wood should be placed in such a way as to maximize surface area, i.e., using 1" boards spaced apart rather than using 4" X 4" posts. The volume of wood used should be 1/100th of the volume of the tank. Three replications of each treatment group should be performed.

b) A control tank system identical to the treatment system should be performed concurrently using, in place of the treated wood, an equal volume and surface area of untreated wood of the same species (untreated control). Additionally, a negative control, using no wood at all, should be performed.

c) The concentration of total chromium, and arsenic, and additional ions should be measured biweekly and the ions should be speciated as to valence state.

d) To insure that the water quality at the beginning of the test is the highest possible, the dilution water, both fresh and salt, should be reconstituted from deionized water and chemicals of at least reagent-grade purity should be used. Refer to "Methods for Acute Toxicity Tests for Fish, Macroinvertebrates and and Amphibians", EPA-660/3-75-009, April 1975. The dilution water should be assayed for chromium, arsenic, and additional ions at test initiation. All other test standards and data reporting should conform to the guidelines for a fish early life-stage test as set forth in EPA's Pesticide Assessment Guidelines: Subdivision E. In this way, both the amount of chromium, arsenic, and additional ions leaching from the wood can be estimated and the subchronic effects of these ions on fish can be determined.

8/ Reserved pending outcome of acute and subchronic aquatic testing.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS FOR CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	N/A	Yes	12 Months
62-2 - Certification of Limits	MP	All	No	N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	N/A	Yes	12 Months

---

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS FOR CHROMATED AND NON CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity -	MP	B	No		Yes[1/]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	B	No		Yes[1/]	9 Months
81-3 - Acute Inhalation Toxicity -	MP	B	No		Yes[1/]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	B	No		Yes[1/]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	B	No		Yes[1/]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	B	No		Yes[1/]	9 Months
81-7- Acute Delayed Neurotoxicity - Hen	MP	B	No		No[2/]	

1/ The studies are to be performed on a rodent other than the rat. The Agency may waive certain acute studies on specific formulations of copper chromated arsenicals if adequate data are already on file for a copper chromated arsenical formulation which the Agency deems applicable, based on close similarity of composition.

2/ The Agency does not ordinarily require neurotoxicity testing of pesticides which are not organophosphates.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	EP	All	No	N/A	Yes[2]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	EP	All	No	N/A	Yes	6 Months
62-2 - Certification of Ingredient Limits	EP	All	No	N/A	Yes	6 Months

---

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each end-use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Only the source and a description of As, Cu, Cr, and any other active ingredients must be provided. This is to include company name and address, product name, percent by weight, and technical data sheets, and EPA Registration Number, if a registered product.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS CONTAINING CHROMATED AND NON-CHROMATED ARSENICALS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity -	EP	B	No		Yes[1/]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	EP	B	No		Yes[1/]	9 Months
81-3 - Acute Inhalation Toxicity -	EP	B	No		Yes[1/]	9 Months
81-4 - Primary Eye Irritation - Rabbit	EP	B	No		Yes[1/]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	EP	B	No		Yes[1/]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	EP	B	No		Yes[1/]	9 Months
81-7- Acute Delayed Neurotoxicity - Hen	EP	B	No		No[2/]	

1/ The studies are to be performed on a rodent other than the rat. The Agency may waive certain acute studies on specific formulations of copper chromated arsenicals if adequate data are already on file for a copper chromated arsenical formulation which the Agency deems applicable, based on close similarity of composition.

2/ The Agency does not ordinarily require neurotoxicity testing of pesticides which are not organophosphates.

II. LABELING APPENDICES

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with differen registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

   "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PEST/DIS-2

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST [40 CFR 261.33(e)] (with RCRA # and CAS #)

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

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II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Consumer Information Sheet

INORGANIC ARSENICAL PRESSURE-TREATED WOOD

(Including: CCA, ACA, and ACZA)

CONSUMER INFORMATION

This wood has been preserved by pressure-treatment with an EPA-registered pesticide containing inorganic arsenic to protect it from insect attack and decay. Wood treated with inorganic arsenic should be used only where such protection is important.

Inorganic arsenic penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to inorganic arsenic may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use or dispose of the treated wood.

USE SITE PRECAUTIONS

Wood pressure-treated with waterborne arsenical preservatives may be used inside residences as long as all sawdust and construction debris are cleaned up and disposed of after construction.

Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

Do not use treated wood for cutting-boards or countertops.

Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

Treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS

Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves, fireplaces, or residential boilers because toxic chemicals may be produced as part of the smoke and ashes. Treated wood from commercial or industrial use (e.g., construction sites) may be burned only in commercial or industrial incinerators or boilers in accordance with state and Federal regulations.

Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dust mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

When power-sawing and machining, wear goggles to protect eyes from flying particles.

After working with the wood, and before eating, drinking, and use of tobacco products, wash exposed areas thoroughly.

If preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household clothing.

Approved by the U.S. Environmental Protection Agency

III. USE INDEX APPENDIX

c006801

ARSENIC ACID*

TYPE PESTICIDE: Fungicide (Refer also to Desiccant entry)

FORMULATIONS:
FI (75%)
SC/L (3%, 21%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Individuals who enter pressure treatment cylinders and other related equipment that are contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program. Refer to appropriate labeling for details of the PEL Monitoring Program. Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.

Definition of Terms:
w/w - weight to weight

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*orthoarsenic acid

ARSENIC ACID

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Wood or Wood Structure Protection Treatments)		
/640100A	Wood Protection Treatment to Forest Products by Pressure		
FYAEQBB	Wood rot/decay	[MAI] 0.0002-0.0024 lb a.i./ application (3% SC/L)	Vacuum-pressure impregnation. Dilute with water to concentrations of 0.5 percent (w/w) to 0.8 percent (w/w) depending on retention desired. Kiln dry after treatment or allow 1 week between impregnation and installation for fixation of preservative. Formulated with copper sulfate and sodium dichromate.
		[MAI] 0.0011-0.0168 lb a.i./ application (21% SC/L)	Vacuum-pressure impregnation. Dilute with water to concentrations of 0.5 percent (w/w) to 8 percent (w/w) depending on retention desired. Kiln dry after treatment or allow 1 week between impregnation and installation for fixation of preservative. Formulated with chromic acid and cupric oxide.

Listing of Registered Pesticide Products by Formulation

&075.0002 75% formulation intermediate
arsenic acid (006801)
000061-00171 003098-00016

&203.0015 3% soluble concentrate/liquid
arsenic acid (006801), copper sulfate (024401) plus sodium dichromate (068304)
045968-00004

&221.0015 21% soluble concentrate/liquid
arsenic acid (006801), chromic acid (021101) plus cupric oxide (042401)
045968-00005

ARSENIC ACID

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
021101	—	chromic acid
024401	—	copper sulfate
042401	—	cupric oxide
068304	—	sodium dichromate

— Use EPA Acceptable Common/Chemical Name

c013601

AMMONIUM ARSENATE

TYPE PESTICIDE: Insecticide, Fungicide

FORMULATIONS: RTU (7.7%)

GENERAL WARNINGS AND LIMITATIONS: None.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Wood or Wood Structure Protection Treatments)		
/640030A	Wood Protection Treatment (exposed surfaces of pressure treated lumber)		Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood). Applicators must wear disposable coveralls (e.g., vinyl or polyethylene) or other similar impermeable clothing during the application process where dermal contact is expected.
IMGAAAA FYAEQBB	Termites Wood rot/decay	7.7% solution (7.7% RTU)	Commercial or industrial use only. Wood protection treatment to exposed surfaces of pressure treated lumber. Stir contents and use full strength. Apply several coats with brush or rag mop to all surfaces of pressure treated lumber that have been exposed by cutting, notching or dapping. Formulated with copper (in the form of an ammonia complex).

AMMONIUM ARSENATE

Listing of Registered Pesticide Products by Formulation

§207.7016 7.7% liquid-ready to use

ammonium arsenate (013601) plus copper (in the form of an ammonia complex) (022702)

003098-00003 011351-00001*

*currently unavailable for review

c006802

ARSENIC PENTOXIDE

TYPE PESTICIDE: Insecticide, Fungicide, Molluscicide

FORMULATIONS:
SC/S (10%, 26.9%, 30.5%)
SC/L (7.3%, 8.2%, 9.84%, 9.9%, 16.6%, 16.88%, 17%, 17.6%, 18%, 18.04%, 18.2%, 19%, 20.25%, 23.8%, 24.48%, 24.5%, 32.5%, 34%)
RTU (4.08%)

GENERAL WARNINGS AND LIMITATIONS: None.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Wood or Wood Structure Protection Treatment)		
/640030A	Wood Protection Treatment of Pressure Treated Wood that has been Exposed through Fabrication or Damage		Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood). Applicators must wear disposable coveralls (e.g., vinyl or polyethylene) or other similar impermeable clothing during the application process where dermal contact is expected.
IMGAAAA FYAEQB3	Termites Wood rot/decay	4.08% solution (4.08% RTU)	Commercial or industrial use only. Wood protection treatment to pressure treated wood. Brush into all cut or machined surfaces and allow to soak into the wood. Formulated with chromic acid, cupric oxide.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/640100A	Wood Protection Treatment by Pressure (forest products)		RESTRICTED USE PESTICIDE. For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors). Individuals who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations. Individuals in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is

Wood Protection Treatment by Pressure (forest products) (continued)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
			unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program. Note to user - Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.
IMGAAAA FYAEQBB	Termites Wood rot/decay	0.045-1.9% solution (10%, 26.9%, 30.5% SC/S) (8.2-34% SC/L)	Wood protection treatment by pressure. Formulated with one or a combination of: chromic acid, copper sulfate, cupric oxide, potassium dichromate, sodium dichromate, and sodium pyroarsenate.
		No dose given; refer to instructions by American Wood Preservation Assn. (8.2%, 9.84%, 16.6%, 16.88%, 17%, 18%, 18.2%, 20.25%, 24.5%, 34% SC/L)	Wood protection treatment by pressure. Formulated with chromic acid, and cupric oxide.
IMGAAAA FYAEQBB	Termites Wood rot/decay	0.073-0.585% solution (7.3% SC/L)	

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/690190A	Wood Protection Treatment to Wood Intended for Use in the Construction of Boats, Ships, and Marine Structures		RESTRICTED USE PESTICIDE. For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors). Individuals who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations. Individuals in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Wood Protection Treatment to Wood Intended for Use in the Construction of Boats, Ships, and Marine Structures (continued)		
			unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program. Note to user - Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.
IFAAHA GEAAGA	Limnoria Teredos	0.073-0.585% solution (7.3% SC/L)	Wood protection treatment by pressure. Formulated with chromic acid, and cupric oxide.

ARSENIC PENTOXIDE

Listing of Registered Pesticide Products by Formulation

6010.0015 10% soluble concentrate/solid
arsenic pentoxide (006802), copper sulfate (024401) plus potassium dichloride (068302)
000061-00127

6026.9015 26.9% soluble concentrate/solid
arsenic pentoxide (006802), copper sulfate (024401) plus sodium dichromate (068304)
000061-00140

6030.5015 30.5% soluble concentrate/solid
arsenic pentoxide (006802), sodium pyroarsenate (013401), copper sulfate (024401) plus sodium dichromate (068304)
000061-00139

6207.3015 7.3% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00042

6208.2015 8.2% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
047097-00001

6209.8415 9.84% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
047097-00002

6209.9015 9.9% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
010465-00011

6216.6015 16.6% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
035896-00002

6216.8815 16.88% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
047097-00003

6217.0015 17% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
000061-00128 003008-00036 010356-00006 048706-00001

Listing of Registered Pesticide Products by Formulation (continued)

&217.6015 17.6% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
010465-00012

&218.0015 18% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00035

&218.0415 18.04% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
000061-00170

&218.2015 18.2% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
008333-00002

&219.0015 19% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
010465-00010

&220.2515 20.25% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
047097-00004

&223.8015 23.8% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
000061-00141*
*jacket currently unavailable for review

&224.4815 24.48% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
000061-00173

&224.5015 24.5% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00017

&232.5015 32.5% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00034*
*jacket currently unavailable for review

Listing of Registered Pesticide Products by Formulation (continued)

6234.0015 34% soluble concentrate/liquid
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00016 008333-00001

6204.0816 4.08% liquid-ready to use
arsenic pentoxide (006802), chromic acid (021101) plus cupric oxide (042401)
003008-00021

9999999 State Label Registration

HI Reg. No.
035053-05242 036019-03490

c013401

SODIUM PYROARSENATE

TYPE PESTICIDE: Insecticide, Fungicide

FORMULATIONS: SC/S (6.2%)

GENERAL WARNINGS AND LIMITATIONS: For industrial use only.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Wood or Wood Structure Protection Treatments)		
/640100A	Wood Protection Treatment by Pressure (forest products)		RESTRICTED USE PESTICIDE. For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors). Individuals who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or

Wood Protection Treatment by Pressure (forest products) (continued)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
			boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations. Individuals in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program. Note to user - Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene. A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed systems is defined as any containment which prevents the release of subject chemicals into the surrounding external environment, except that the release of incidental amounts of chemical during equipment loading and periodic clean-out or maintenance operations shall not be deemed a breach of containment.
IYGAAAA FYAEQBB	Termites Wood rot/decay	0.062-0.31% solution (6.2% SC/S)	Wood protection treatment by pressure. Formulated with arsenic pentoxide, copper sulfate, and sodium dichromate.

SODIUM PYROARSENATE

Listing of Registered Pesticide Products by Formulation

6006.2015 6.2% soluble concentrate/solid

sodium pyroarsenate (013401), arsenic pentoxide (006802), copper sulfate (024401) plus sodium dichromate (068304)

000061-00139

c013505

SODIUM ARSENATE*

TYPE PESTICIDE: Insecticide, Fungicide

FORMULATIONS:
Tech (98%, 98.88%)
SC/S (23.8%, 23.9%)
RTU (1.4%)

GENERAL WARNINGS AND LIMITATIONS:
Agricultural Tolerances:
Grapes - 3.5 ppm

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Wood or Wood Structure Protection Treatment)		
/640100A	Wood Protection Treatment by Pressure (forest products)		RESTRICTED USE PESTICIDE. For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors). Individuals who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing, including overalls, jacket, gloves, and boots, impervious to the wood treatment formulation. In addition, individuals who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per

*disodium arsenate

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Wood Protection Treatment by Pressure (forest products) (continued)

cubic meter of air (10ug/m3) averaged over an 8-hour work period. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with state and federal regulations.

Individuals in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators, MSHA/NIOSH-approved for inorganic arsenic, if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10ug/m3) averaged over an 8-hour work period. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) Monitoring Program.

Note to user - Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jacket, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.

A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed systems is defined as any containment which prevents the release of subject chemicals into the surrounding external environment, except that the release of incidental amounts of chemical during equipment loading and periodic clean-out or maintenance operations shall not be deemed a breach of containment.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Wood Protection Treatment by Pressure (forest products) (continued)		
IMGAAAA FYAEQBB	Termites Wood rot/decay	0.119-1.19% solution (23.8% SC/S)	Wood protection treatment by pressure. Use only in vacuum pressure impregnation of forest products. Formulated with sodium pentachlorophenate, sodium chromate and sodium fluoride.
		0.239-1.195% solution (23.9% SC/S)	Wood protection treatment by pressure. Formulated with 2,4-dinitrophenol, sodium chromate and sodium fluoride.
'640020A	Wood Protection Treatment of Seasoned Forest Products		Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood). Applicators must wear disposable coveralls (e.g., vinyl or polyethylene) or other similar impermeable clothing during the application process where dermal contact is expected.
:GAAAA AEQB3	Termites Wood rot/decay	-- (1.4% RTU)	Commercial or industrial use only. Wood protection treatment of seasoned forest products. Use only for application to exposed surfaces when cutting, notching or dapping pressure treated lumber. Apply several coats undiluted with brush or rag mop to all surfaces of lumber that have been exposed by cutting, notching or dapping. Formulated with 2,4-dinitrophenol, sodium chromate, pyridine and sodium fluoride.

SODIUM ARSENATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/640010A	Wood Protection Treatment of Unseasoned Forest Products		
IMGAAAA	Termites	--	Wood protection treatment of unseasoned forest products. Use as a diffusion treatment in water solutions having hydrometer readings from 1.13 to 1.37. Formulated with 2,4-dinitrophenol, sodium chromate and sodium fluoride.
FYAEQBB	Wood rot/decay	(23.9% SC/S)	

SODIUM ARSENATE

Listing of Registered Pesticide Products by Formulation

098.0001 98% technical chemical
  sodium arsenate (013505)
    015135-00001

098.8801 98.88% technical chemical
  sodium arsenate (013505)
    003008-00029

023.8015 23.8% soluble concentrate/solid
  sodium arsenate (013505), sodium pentachlorophenate (063003), sodium chromate (068303) plus sodium fluoride (075202)
    000061-00124

023.9015 23.9% soluble concentrate/solid
  sodium arsenate (013505), 2,4-dinitrophenol (037509), sodium chromate (068303) plus sodium fluoride (075202)
    000061-00110 000061-00134

201.4016 1.4% liquid-ready to use
  sodium arsenate (013505), 2,4-dinitrophenol (037509), sodium chromate (068303), pyridine (069202) plus sodium fluoride (075202)
    000061-00111

999999 State Label Registration

  HI Reg. No.
    035053-05213

007001

ARSENIC TRIOXIDE*

TYPE PESTICIDE: Antifoulant, Herbicide, Insecticide, Rodenticide

FORMULATIONS:
Tech (90%, 94%, 99%, 99.5%)
FI (37%, 99%)
WP (20%)

GENERAL WARNINGS AND LIMITATIONS: None.

	Site, Dosage and Formulation	Tolerance, Use, Limitations
	DOMESTIC OUTDOOR	
	(Wood or Wood Structure Protection Treatment)	
640020A	Wood Poles	
MGAAAA	Termites	
	2 lb a.i./gal (20% WP)	Impregnation treatment. Mix product with water to form a smooth paste. Vertical punctures should be made at 4 inch intervals. Inject all the paste contained in the piston sheath into the punctures. Formulated with 2,4-dinitrophenol and sodium fluoride.

*arsenous oxide

ARSENIC TRIOXIDE

Listing of Registered Pesticide Products by Formulation

5090.0001 **90% technical chemical**
arsenic trioxide (007001)
009777-00001

5094.0001 **94% technical chemical**
arsenic trioxide (007001)
003840-00005 004581-00259

5099.0001 **99% technical chemical**
arsenic trioxide (007001)
001439-00189

5099.5001 **99.5% technical chemical**
arsenic trioxide (007001)
007401-00202

5037.0002 **37% formulation intermediate**
arsenic trioxide (007001) plus copper (metallic) (022501)
003098-00015

5099.0002 **99% formulation intermediate**
arsenic trioxide (007001)
000255-00025

5020.0006 **20% wettable powder**
arsenic trioxide (007001), 2,4-dinitrophenol (037509) plus sodium fluoride (075202)
003231-00001

IV. BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Chromated and Non-Chromated Arsenical Wood Preservatives Standard

MRID	CITATION
00099363	Fink, R.; Reno, F.E. (1973) Final Report: Acute LC50--Bluegill Sunfish and Rainbow Trout: Taco CCA, 40% Concentrate: Projects No. 829-100 and No. 829-101. (Unpublished study received Aug 20, 1973 under 8333-1; prepared by Environmental Sciences Corp., submitted by Rentokil, Inc., Spartanburg, N.C.; CDL:128552-B)
00104601	Wolven, A.; Levenstein, I. (1970) To Determine If the Test Material Produces Any Irritation When Instilled into Rabbits' Eyes: Assay No. 10100. (Unpublished study received Oct 27, 1970 under 390-43; prepared by Leberco Laboratories, submitted by Pettit Paint Co., Inc., Borough of Rockaway, NJ; CDL:003224-B)
00106113	Fink, R. (1973) Final Report: Eight-day Dietary LC50--Bobwhite Quail: Taco CCA: Project No. 829-102. (Unpublished study received Aug 20, 1973 under 8333-1; prepared by Environmental Sciences Corp., submitted by Rentokil, Inc., Spartanburg, N.C.; CDL:128552-C)
00120843	Peoples, S. (1979) The Dermal Absorption of Arsenic in Dogs from Sawdust from Wood Treated with ACA and CCA-C. (Unpublished study received Aug 27, 1979 under unknown admin. no.; prepared by Univ. of California--Davis, Dept. of Physiological Science, submitted by Koppers Co., Inc., Pittsburgh, PA; CDL:240889-B)
00159870	Jacobson-Kram, D.; Mushak, P.; Piscator, M.; et al. (1984) Health Assessment Document for Inorganic Arsenic: Final Report: EPA-600/8-83-021F. Washington, DC: Environmental Protection Agency. 347 p.
GS0647-001	Woolson, E.; Gjovik, L. (1981) The Valence State of Arsenic on Treated Wood. American Wood-Preservers' Association [Proceedings of 1981 Annual Meeting]. 5 p.
GS0647-002	US Environmental Protection Agency (1984) Health Assessment Document for Chromium: Final Report: EPA-600/8-83-014F. 180 p.

V. FORMS APPENDICES

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-8

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to ente into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following require items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to b bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ______________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ________________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________________

Date ______________ Title ______________________________

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